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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,040	10/17/2000	Michael Seul	464.1006CON4	3560

7590 10/11/2002

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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/11/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/690,040

Applicant(s)

SEUL, MICHAEL

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-69 is/are pending in the application.
- 4a) Of the above claim(s) 57-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,7,8,10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 43-56, in Paper No. 14 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43, line 1, please distinguish the first occurred "biomolecules" and the second occurred "biomolecules", i.e. are these the same biomolecules or different?

Claim 43 is confusing because it recites that the bead types are distinguished by the biomolecules and each bead type is associated with a unique chemical/physical characteristic that identifies the biomolecules. If the biomolecules are the key to distinguish between the bead types, then to what does the unique chemical/physical characteristic belong to? To the beads or to the biomolecules? And why does one need the unique characteristic to identify the biomolecules while the biomolecules are distinguishable among themselves.

Claims 54 and 55 do not further limit the independent claims because these claims recites a method step, particularly using a device to detect the signal of the labels. These devices or means for detection are not treated as being part of the

composition in the independent claim. Furthermore, optical microscopy includes using a device such as a charged-couple device to record the optical signal generated by the labels. Thus, claims 54 and 55 are confusing in reciting using a recording device such as a CCD in conjunction with a means of optical microscopy.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 43-47, 50-53, 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Chandler et al. (WO 99/19515).

Chandler teaches 64-subset bead collection (array of claim 50) or 64 populations (subarray) of beads, each population differing from another. Each subset/population is encoded with a mixture of at least two fluorescent dyes. The proportion or ratio of such two dyes distributed within a single bead of each population is varied. The specific ratio or proportion of dyes at which they are mixed within a population of beads will determine the location of said populations on a fluorescence map, which allocates these populations according to fluorescent color and brightness. These beads are bound to assay reactants such as antibodies, antigens, or nucleic acid probes to detect analytes

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such proteins, antigens, antibodies, nucleic acids, enzymes. Multiplexed analytes can be detected at the same time using these beads, for examples analytes such as particular antigen, e.g. series of grass allergen, various substance of drug abuse etc. (see page 4, line 3-page 5, line 3; page 8, line 30-page 9, line 8; page 20, line 5-25). These bead populations are easily discriminated as essentially non-overlapping clusters by visual detection methods such as microscopy. Thus, it is inherent that the bead populations are in a planar array so that there is no overlapping clusters.

Claims 43, 47, 49-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Walt (WO99/18434).

Walt teaches a microsphere-based analytical chemistry system in which self-encoding microspheres having distinct characteristic optical response signatures to specific target analytes may be mixed together while the ability is retained to identify the sensor type and location of each sensor in a random dispersion of large numbers of such sensors in a planar sensor array using optically interrogatable encoding scheme. The composition comprises a substrate – any material that can be modified to contain discrete individual sites appropriate for the attachment or association of beads and is amenable to at least one detection method. The possible substrate are silicon, modified silicon etc. (see page 13, second paragraph). On these substrates are bead subpopulations which are selected based on distinguishable differences in their characteristic optical response signatures when illuminated by excitation light in the presence of a target analyte. The beads also comprise a reporting dye which provides an optical response signature that can be used to identify the bead, and thus the

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attached bioactive agent. The bioactive agents (binding ligand for analytes) comprises proteins, polypeptides, oligopeptides, nucleic acids. The target analytes are biomolecules such as receptors, antigens, antibodies, nucleic acids, polypeptides and proteins. (see page 37, 3rd paragraph; page 21, 2-4 paragraphs.) Detecting the optical signal of the labels is performed by illuminating the beads with excitation energy and the response of the bead is recorded with a charged-couple device camera (CCD). (see examples 17 and 18). With respect to claim 54 and 55, Walt teaches a means of optical microscopy such as a CCD.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler or Walt further in view of Koopal et al. (US 5,442,246).

Chandler and Walt have been discussed above.

However, Chandler and Walt do not teach the array of beads on an electrode.

Koopal teaches electrode coated with a layer of latex particles (polymer coating) bound with redox enzyme. Such an electrode is useful in conducting enzymatic assays. (see col. 3, line 1-col. 4, line 45).

It would have been obvious to one of ordinary skills in the art to coat the particles/beads of Chandler or Walt on the electrode as taught by Koopal since

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Chandler and Walt teach using enzymes as labels coupled to beads for detecting a target analyte. Thus, one of ordinary skills in the art would find it obvious to coat the particles/beads comprising of labels on a substrate such as an electrode so that mass detection of the particles immobilized on the electrode can be detected sufficiently and sensitively. Optical activity can also be amplified.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
October 3, 2002


LONG V. LE
SUPERVISORY PATENT EXAMINER
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09/10/02